REMARKS/ARGUMENTS

The present reply is responsive to the final Office Action dated March 25, 2010. Claims 1, 12 and 14 have been amended. No new matter has been introduced by these amendments. A petition for a one month extension of time and a Request for Continued Examination accompany this reply. The rejections will be addressed in view of the claims as presented herein.

Reexamination and reconsideration of the above-identified application, pursuant to and consistent with 37 C.F.R. § 1.116 and in light of the following amendments and remarks, are respectfully requested. Good cause exists for the entry of this amendment in accordance with 37 C.F.R. § 1.116.

As an initial matter, the applicant would like to thank the Examiner for her telephone interview with the undersigned attorney on June 21, 2010. The interview summary dated June 25, 2010 accurately reflects the discussion that was held.

Turning to the Office Action, claims 1-3 and 14-16 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,937,853 ("*Strom*") in view of U.S. Patent Publication No. 2002/0014239 ("*Chalvignac*") and U.S. Patent No. 3,961,627 ("*Ernst*"). Claims 4-6 were rejected under 35 U.S.C. § 103(a) as being obvious over *Strom*, *Chalvignac* and *Ernst* as applied to claim 1 on page two of the Office Action, and further in view of U.S. Patent No. 5,307,795 ("*Whitwam*"). Claims 7-9 were rejected under 35 U.S.C. § 103(a) as being obvious over *Strom*, *Chalvignac* and *Ernst* as applied to claim 1 and further in view of U.S. Patent No. 5,308,040 ("*Torres*"). Claims 10 and 12 were rejected under 35 U.S.C. § 103(a) as being obvious over *Strom*, *Chalvignac* and *Ernst* as applied to claim 1 and further in view of U.S. Patent No. 5,813,410 ("*Levin*"). Claim 11 was rejected under 35 U.S.C. § 103(a) as being obvious over *Strom*, *Chalvignac, Ernst,* and *Levin* as applied to claim 10 on page nine (9) of the Office Action, and further in view of

U.S. Patent No. 6,102,038 ("*DeVries*"). Claim 13 was rejected under 35 U.S.C. § 103(a) as being obvious over *Strom*, *Chalvignac*, *Ernst*, and *Levin* as applied to claim 12 on page nine (9) of the Office Action, and further in view of U.S. Patent No. 5,735,267 ("*Tobia*"). Of these, claims 1, 12 and 14 are independent. Applicant respectfully traverses these rejections.

Strom, *Chalvignac*, *Ernst* and *Levin* were discussed in the prior reply of January 22, 2010. For the sake of brevity, those discussions are incorporated by reference herein. In view of the interview, applicant first focuses on the deficiencies of *Strom*. As acknowledged in the pending rejection, *Strom* has several deficiencies such as its silence "as to inhalation and exhalation valves, the inhalation valve being controlled by an automatic control unit separate from a comparator and receiving signals from the sensors" and that it "does not give details as to the pressurized gas source." (Office Action, p.2).

According to the rejection of independent claims 1 and 14, *Strom* allows "real time transmission of a pressure or flow signal for determining barometric or volumetric mode operation (see column 4, lines 19-28) and controlling the operation of the gas source (see Figure 1)." (Office Action, p.2). Applicant respectfully disagrees. As discussed during the interview, as best understood, *Strom* is merely able to switch between a supported ventilation mode and a controlled ventilation mode when an apnea is detected, for instance by carrying out a predetermined sequence before switching modes back and forth. For instance, *Strom* explains:

> Thus the ventilator according to the invention is automatically switched, in response to respiratory efforts of the patient, to an operation mode in which the spontaneous respiration of the patient is supported to obtain sufficient ventilation. In the case of an apnea exceeding a predetermined length of time, the ventilator is switched to operate according to prescribed parameter values so as to also in this situation obtain sufficient ventilation of the patient. Thus, every apnea will also be backed up, making the ventilator safe in this respect.
>
> (2:48-57)

Depending on prescribed parameter values set by the

operator before operation of the ventilator, the ventilator will either work in pressure or volume support.

> The sensing unit senses respiration efforts of the patient and supplies a signal to the regulating unit to cause the regulating unit to adapt an operation cycle of the gas delivery unit to the sensed respiration efforts of the patient, and then to cause the gas delivery unit to deliver an auxiliary support which makes up any deficiency from a predetermined total value of a particular respiration parameter.
>
> The auxiliary support may be in the form of additional volume if the predetermined total parameter in question is a volume level, or can be a delivery of additional pressure, if the predetermined total parameter is a pressure level.
>
> (2:28-40)

See also *Strom* at column 4, lines 47-53, at column 5, lines 24-30, and column 6, lines 16-27. While such a ventilator may work in either a barometric or volumetric mode, *Strom* does not disclose or suggest a switch having a position which determines a barometric or volumetric mode of the apparatus between or during the inhalation and expiratory phases as in the inventions of independent claims 1, 12 and 14.

For instance, claim 1 has been amended to recite, in part, a "switch configured for real time selective connection of the comparator with the pressure sensor or the flow rate sensor, allowing real time transmission of a pressure signal or flow rate signal, the position of said switch determining a barometric or volumetric mode of the apparatus **between or during the inhalation and expiratory phases**." Claims 12 and 14 includes equivalent amendments.

Such a feature provides flexibility in the apparatus to switch modes as needed in real time. For instance, the specification explains in one example that "the association of a direct closed regulation loop for the selection of a reference value parameter with a valve permitting proportional operation, allows real time control of barometric and volumetric operating modes of the apparatus, between the inhalation and expiratory phases and during these phases." (Page 8, line 29 to page 9,

line 2).

This important difference allows the claimed ventilator to switch in real time between barometric and volumetric modes, even during the inhalation or expiratory phases, and even during the implementation of a particular mode. With these features, the claimed ventilator can for instance implement a Volume Assured Pressure Support ("VAPS") mode. In this mode, the ventilator starts its operation in barometric mode, monitors the volume supplied to the patient with respect to a target and automatically switches to volumetric mode if the supplied volume is insufficient. This is explained at page 16, lines 1-20 of the specification as filed:

> As mentioned above, the configuration presented above allows among others the operation according to different modes (and a change of the respiratory mode in real time within a given respiratory cycle).
>
> For example, it is possible to operate the apparatus in VAPS (Volume Assured Pressure Support) mode in real time. Such a mode uses the barometric mode and can transfer the mode to a volumetric mode in real time - including within a same inhalation or expiratory cycle.
>
> More precisely, in this mode, an inhalation phase comprises:
>
> • at the beginning, operation in barometric mode,
>
> • an algorithm then monitors the volume of respiratory gas supplied to the patient on a constant basis, and extrapolates the volumes already supplied during the inhalation phase to determine if in a given predetermined time, a pre-determined target volume will be indeed supplied to the patient during this phase.
>
> • if the algorithm determines that this is not the case, the operation of the apparatus is forced into volumetric mode to supply the patient with a volume which permits this target to be met.
>
> It is clear that in such a mode, the switch 152 plays an important role 20 (in particular for the forced mode change mentioned).

The rejections rely on *Chalvignac* to supply inhalation and exhalation valves. *See* Office Action at p.3. Applicant respectfully submits there is no proper motivation for the applied combination, and that reliance on *Chalvignac* would not overcome the deficiencies of *Strom*.

On the contrary, this would lead to additional control

systems in order to control the opening of these valves. This would also lead to conflicts with the control of the gas source itself during operation. In particular, the controlled and supported ventilation mode of *Strom* would be disturbed by the introduction of valves, which would modify the pressure or flow rate in the exhalation or inhalation ducts. Even if one could combine the teachings of *Chalvignac* with those of *Strom*, it would not result in the inventions of claims 1, 12 and 14, since these references do not disclose a comparator and a switch which determines barometric or volumetric mode of the apparatus between or during the inhalation and expiratory phases.

The rejection states that one of ordinary skill could have used the teachings of *Ernst* in the modified ventilator of *Strom/Chalvignac*. However, *Ernst* cannot cure the deficiencies of *Strom/Chalvignac*. While *Ernst* discloses a comparator (7 in FIG. 1), the mere disclosure of a comparator is insufficient. *Ernst* discusses its comparator as follows:

> The valve control 6 itself receives a control signal from a comparator circuit 7, in which the nominal and actual values for the flow and pressure of the respiration gas are compared with one another. The actual values are delivered to this circuit in the form of electrical signals, which the measuring device derives from the flow and pressure values measured. The nominal values come from a logic circuit 8, to which the actual values are likewise delivered. The logic circuit 8 has, apart from the input for the actual values, a series of inputs which are symbolized by the arrow 9 and come from the external control elements. The logic circuit 8 also has a series of outputs which are symbolized by the arrow 10 and which lead to indicator units or alarm devices. The comparator circuit 7 and the logic circuit 8 together represent a regulator in the sense of the present invention. It is to be observed that the comparator circuit 7 represented in simplification in FIG. 1, in reality consists of two comparator circuits since the flow and pressure of the respiration gas are regulated separetely
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> (4:5-25)

The structure of *Ernst* is not what is claimed. In contrast to the architectures recited in claims 1, 12 and 14, in *Ernst* the comparator sends a control signal to the control valve (4) through a valve control (6) for modulating said control valve (4).

In view of the above, applicant submits that independent claims 1, 12 and 14 are not obvious in view of *Strom*, *Chalvignac* and *Ernst* (or *also* in view of *Levin* with respect to claim 12.

Furthermore, applicant submits that claim 12 is further patentable over the applied combination for the following reasons.

Claim 12 describes the operation of a micro turbine and the closing of the expiratory valve based on the micro-turbine to regulate a positive expiratory pressure during the expiratory phases. The use of a micro turbine in combination with the expiratory valve is very advantageous. It does not generate unwanted side effects (vibrations, operating anomalies, etc.), and thus permit dispensing with additional means (e.g., filters) that are usually positioned between the auxiliary pressure source and the expiratory valve. *See* specification at page 17, lines 1-9.

The rejection of claim 12 acknowledges that the combination of *Strom*, *Chalvignac* and *Ernst* does not disclose a micro-turbine as claimed. As best understood, *Strom* neither describes an expiratory valve nor a micro-turbine. *Chalvignac* does not disclose or suggest the use of a micro turbine, but instead describes a fan (paragraph 0043), which is a common auxiliary pressure source. And *Ernst* does not teach or suggest the use of a micro turbine. It thus appears that none of the ventilators cited in these references describes the use of a micro-turbine in combination with an expiratory valve, in order to regulate a positive expiratory pressure during the expiratory phases.

Levin admittedly describes the use of a micro-turbine in an internal body pump. However, applicant respectfully submits that the mere disclosure of a micro-turbine in an internal body pump does not provide a proper motivation for one of ordinary skill in the art to connect *Levin's* micro-turbine to an expiratory valve in a ventilator in the manner claimed. As best understood, none of the cited documents that describe a ventilator disclose or otherwise suggest the use of a micro-

turbine as claimed. Applicant submits that there is no proper motivation to modify the combination of *Strom*, *Chalvignac* and *Ernst* with *Levin*. In view of this, applicant submits that claim 12 is patentable over the applied combination.

Finally, claims 2-11, 13 and 15-16 depend from independent claims 1, 12 and 14, respectively, and contain all the limitations thereof. For at least the reasons presented above, applicant submits that these dependent claims are likewise patentable.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which she might have. If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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